# CLINICAL AND RADIOGRAPHIC EVALUATION OF SINUS FLOOR AUGMENTATION UTILIZING IRRADIATED CANCELLOUS BONE ALLOGRAFT, USING SINUS-LIFT BALLOON SYSTEM- A 6 MONTHS STUDY

*Dissertation submitted to*

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*In partial fulfillment for the Degree of*

**MASTER OF DENTAL SURGERY**

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**PERIODONTICS**

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# CERTIFICATE

This is to certify that this dissertation titled **"CLINICAL AND RADIOGRAPHIC EVALUATION OF SINUS FLOOR AUGMENTATION UTILIZING IRRADIATED CANCELLOUS BONE ALLOGRAFT, USING SINUS-LIFT BALLOON SYSTEM – A 6 MONTHS STUDY"** is a bonafide record of work done by **Dr. D.RADHA BHARATHI** under my guidance during the study period of 2009-2012.

This dissertation is submitted to **THE TAMIL NADU DR. MGR MEDICAL UNIVERSITY** in partial fulfilment for the degree of **MASTER OF DENTAL SURGERY, BRANCH II- PERIODONTOLOGY**. It has not been submitted (partial or full) for the award of any other degree or diploma.

26.12.2011

RAGAS DENTAL COLLEGE & HOSPITAL CHENNAI

**Dr. T.S.S Kumar, MDS.,**
Professor and Head,
Department of Periodontology
Ragas Dental College & Hospital
Chennai

Dr. T.S.S. KUMAR. M.D.S.,
Professor and Head,
Department of Periodontics and Implant Dentistry
Ragas Dental College and Hospital
Chennai - 600 119.

**Dr.B.Shivakumar, MDS.,**
Reader and Guide,
Department of Periodontology
Ragas Dental College & Hospital
Chennai

Department of Periodontics,
Ragas Dental College & Hospital
# 2/102, ECR, Chennai-119

**Dr. S.Ramachandran MDS.,**
Principal
Ragas Dental College & Hospital
Chennai

PRINCIPAL
RAGAS DENTAL COLLEGE & HOSPITAL
CHENNAI

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# LIST OF ABBREVIATIONS

1. ABB-Anorganic Bovine Bone
2. ABBM -Anorganic Bovine Bone Matrix
3. BAOSFE-Bone Added Osteotome Sinus Floor Elevation
4. BHA-Bovine Hydroxyapatite
5. BMP- Bone Morphogenetic Protein
6. CEJ-Cemento Enamel Junction
7. CM -Collagen Membrane
8. CT-Computerized Tomography
9. DFDBA-Demineralised Freeze Dried Bone Allograft
10. ECOSFE-Endoscopically Controlled Osteotome Sinus Floor Elevation
11. ELISA-Enzyme Linked Immunosorbent Assay
12. FDBA-Freeze Dried Bone Allograft
13. HA-Hydroxyapatite
14. LA-Local Anaesthesia
15. MBH-Mean Bone Height
16. MCBA-Mineralised Cancellous Bone Allograft

17. MGCSH-Medical Grade Calcium Sulphate Hemihydrate

18. MIAMBE-Minimally Invasive Antral Membrane Balloon Elevation

19. OMSFE-Osteotome Mediated Sinus Floor Elevation

20. OPG-Orthopantomogram

21. PRP-Platelet Rich Plasma

22. RBH-Residual Bone Height

23. RMTB- Rocky Mountain Tissue Bank

24. TGF-β-Transforming Growth Factor Beta

25. VBH-Vertical Bone Height

26. β-TCP- Beta Tricalcium Phosphate

# ABSTRACT

## BACKGROUND

The posterior maxillary segment frequently suffers from insufficient bone mass to support dental implants. Current bone augmentation methods, including the lateral maxillary approach (hinge osteotomy) and sinus elevation by osteotome, have many shortcomings. The purpose of the present study is to present data on the clinical and radiological outcomes of sinus floor elevation procedure, performed using the Sinus-lift balloon system (Zimmer Dental) followed by bone augmentation utilizing irradiated human cancellous bone allograft (Rocky Mountain Tissue Bank, Denver, Co).

## MATERIALS AND METHODS

A total of nine systemically healthy patients (10 sites), 8 males and 1 female, within the age group of 25-60 years requiring maxillary sinus augmentation for implant placement were selected for the study. Pre-operative diagnostic evaluation was done using OPG.

Sinus lift procedure was done under local anesthesia using the Sinus-lift balloon system (Zimmer Dental), yielding > 10 mm of sinus membrane elevation. Augmentation of the sinus was done utilizing the Irradiated Cancellous Bone Allograft (Rocky Mountain Tissue Bank, Denver, Co).

Post operative radiographic assessment of vertical bone gain was done using OPG at 3 months and 6 months follow-up period. Implant fixation was planned after six months of sinus augmentation.

Statistical analysis of the results was done using Paired **t** Test.

## RESULTS

Clinically, no complications were observed during or after the surgical procedure. All patients healed uneventfully with no signs and symptoms of maxillary sinus pathology, observed during the six months period following surgery.

There was a significant increase in the mean bone height (MBH) post operatively at the 3 months follow-up period. At the point A, the MBH increased by 2.3mm, at the point B and C there was an increase of 3.2mm, and 1.8mm respectively, which consistently increased during the 6 months follow up period (point A- 2.7mm, point B- 3.34 mm, point C-2mm) so as to allow implant placement later.

## CONCLUSION

Within the limits of this study, it can be concluded that:

1. This minimally invasive antral membrane balloon elevation (MIAMBE) procedure using Sinus-lift balloon system yielded satisfactory bone augmentation results, while eliminating the complications and discomfort associated with the traditional lateral window technique.
2. Particulate Irradiated cancellous bone allograft (Rocky Mountain Tissue Bank, Denver, Co) augmentation resulted in being bio-compatible and seemed to improve new bone formation in sinus grafting. It can be used as a substitute for autogenous grafts in sinus augmentation procedures.

However, further controlled clinical trials with large sample size should be executed to evaluate the effectiveness and safety of this technique compared to other sinus augmentation procedures.

## KEYWORDS

Maxillary Sinus Augmentation, Sinus-lift Balloon System, Irradiated Cancellous Bone Allograft.

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# INTRODUCTION

Oral rehabilitation with implant supported prosthesis is considered the therapeutic procedure of choice for partially or completely edentulous patients.[91] Osseointegration of dental implants is highly predictable when implants are completely embedded in bone. Sufficient volume and density of alveolar bone for implant integration and load bearing are pre-requisites for a good clinical outcome.[38]

Implant success and primary stability are greatly affected by localized bone density, with implants placed in areas of poorer bone quality associated with high failure rates.[1]

The posterior region of edentulous maxilla frequently presents insufficient bone for rehabilitation by means of endosseous implants. There is an insufficient volume of bone caused by the combination of alveolar bone resorption and pneumatization of the maxillary sinus.[21] According to Lekholm and Zarb‘s classification posterior maxilla often presents type III or type IV bone quality.[35]

Compromised implant primary stability due to the presence of very trabecular (D4) bone in the posterior segments of the maxilla may lead to early implant survival.[45]

In addition, after tooth loss, the periosteum of the schneiderian membrane exhibits increased osteoclastic activity, that can cause bone

resorption which further limits the quantity of bone available for implant placement.[17]

All these factors can significantly limit the placement of dental implants in the posterior edentulous maxilla. The use of short implants may overcome these limitations. The use of wide-diameter short implants can be considered when the sub sinus alveolar bone available is greater than 6mm and the width of alveolus is greater than or equal to 8mm. Increasing the diameter of the implant compensates for the loss of surface available for anchorage and allows a better distribution of occlusal forces.[15] However several studies have shown higher failure rates with standard short implants.[36]

One method that makes implant placement possible in such difficult situations is the augmentation of maxillary sinus using various graft materials.[95] This procedure involves the detachment of schneiderian membrane from the maxillary sinus floor, creating a space filled with grafting material, to promote vertical bone augmentation into the maxillary sinus cavity.

The sinus floor augmentation procedure (lateral window technique) was pioneered and developed by Tatum in 1976 with his results reported in 1986 (**Tatum**) [80]. However Boyne and James were the first to publish their clinical findings in 1980 (**Boyne**) [7]**.** The technique consists of preparation of a window in the buccal sinus wall, medial rotation of the bony wall in conjunction with elevation of the schneiderian membrane and augmentation of the resulting cavity with autogenous bone and /or other grafting materials.

This procedure can provide increased bone volume and height to aid in primary stabilization of one or more endosseous implants.

In 1994, Summers introduced osteotome sinus floor elevation, which is a minimally invasive technique that allows for localized maxillary sinus elevation, in alveolar crest with a residual bone height of 5 - 10 mm.[75] The osteotome technique yields only a modest bone height increment and further can be complicated by membrane perforation and tear.

Though good implant survival rates are being reported with these procedures, the postoperative morbidity seems to be relatively higher. Hence, modifications of these techniques have been suggested by various authors and thus the 'Minimally-invasive Techniques' have come to stay.

**Kfir et al (2006)**[31] reported on a minimally invasive technique for sinus membrane elevation (MIAMBE) which is a modification of osteotome technique using balloon inflator secured into the osteotomy site. Inflation of the balloon, elevated the sinus membrane, followed by bone augmentation and implant placement. MIAMBE resulted in high procedural success, satisfactory bone augmentation, implant survival and less complication rates. Because it is minimally invasive, this technique may be used as an alternative to the existing sinus augmentation procedures.

Various bone graft materials are available for sinus grafting. Autogenous bone grafts are considered to be the gold standard because of its

high biocompatibility, osteoinductive potential and good clinical outcomes, [28] however the harvesting of autogenous bone requires additional surgery at the donor site, which may lead to morbidity.[54]

Therefore the use of bone substitutes has attracted attention. A wide variety of graft materials have been used to augment bone volume within the sinus: demineralised freeze dried bone allograft (DFDBA) [28], hydroxyapatite preparations[69], calcium phosphate preparations[55] and xenografts as well as growth factors embedded different carrier materials.[24]

Irradiated allogenic cancellous bone and marrow particulate (Rocky Mountain Tissue Bank, Denver, Co.), randomly sized between 2-3mm has also been used as a bone substitute for autogenous bone graft.[81] It is a trabecular allograft obtained from the spinal column and treated with 2.5 and 3.8 megarads of radiation. It has been shown that among all available allograft, irradiated bone is the most similar to autogenous bone, in terms of demonstrating rapid replacement and consistent establishment of a reasonable ratio of new bone, with less expense and morbidity than that associated with autogenous material.

The Sinus lift balloon system (Zimmer Dental) was developed to gently elevate the Schneiderian membrane with minimal trauma and without the use of sharp instruments, making sinus augmentation a predictable procedure for implant placement in posterior maxilla.

Hence the present study was undertaken to assess the clinical and radiological outcome of maxillary sinus elevation using Sinus lift balloon system (Zimmer Dental) followed by augmentation of the sinus utilizing Irradiated Cancellous Bone Allograft (RMTB).

# AIMS AND OBJECTIVES

Aim of the present study was:

1. To assess the safety and efficacy of a minimally invasive technique for maxillary sinus elevation using the Sinus lift Balloon system (Zimmer Dental); followed by augmentation of the sinus with Irradiated Cancellous Bone Allograft (RMTB).

2. To evaluate the clinical and radiological outcomes of sinus floor augmentation procedure using OPG, over a six months period.

# REVIEW OF LITERATURE

## ANATOMY AND PHYSIOLOGY OF THE MAXILLARY SINUS

The maxillary sinus (Antrum of Highmore) is the largest of paired paranasal sinuses, pyramidal in shape and is the first to develop, at 10 weeks in utero. Typical average dimensions of the sinus are height 36 to 45 mm, width 25 to 35 mm and length 38 to 45 mm. Each maxillary sinus has a volume of approximately 15cc. (**Van Den Bergh 2000**)[89].

The maxillary sinus is surrounded by six walls (**Misch CE 1999**)[47].

1. The anterior wall consists of thin, compact bone above the apex of the canine teeth and may extend to the lateral piriform rim of the nose. The anterior wall contains the infraorbital nerve and blood vessels to the anterior teeth.

2. The superior wall is very thin and makes up the orbital floor. A bony ridge contains the infraorbital canal with the nerve and blood vessels.

3. The posterior wall corresponds to the pterygomaxillary region, which separates the antrum from the pterygopalitine fossa. It contains the posterior superior alveolar nerve and blood vessels, including the pterygoid plexus of veins and internal maxillary artery.

4. The medial wall separates the sinus from the nasal fossa. The maxillary ostium drains into the middle meatus of the nasal cavity.

5. The sinus floor may extend between the roots of the maxillary molars. The floor may be 10 mm below the floor of the nasal cavity.

6. The lateral wall forms the posterior maxillary and zygomatic process. This wall provides access for the sinus graft procedure.

**Vasculature:**

The medial wall derives its arterial supply from nasal mucosal vasculature. This comes from branches of the sphenopalatine artery; posterior lateral nasal and posterior septal branches. The frontal, lateral and inferior walls derive their arterial supply from the osseous vasculature (infraorbital, facial and palatine arteries). The medial sinus wall drains through the sphenopalatine vein. All other veins drain through the pterygomaxillary plexus. Innervation is provided by nasal mucosa nerves and the superior alveolar and infraorbital nerves (**Moss-Salentija 1985**)[50].

The sinus may invade the alveolar bone surrounding the roots of the posterior maxillary teeth where it may pose a surgical hazard when extracting teeth in this area.

**Maxillary sinus septa:**

The formation of septa (Underwood's cleft), both incomplete and complete within the sinus is often noted. Septa have been located in 31.7% of

the maxillary sinuses in the premolar area, and they usually do not compartmentalize the antrum (**Tiwana 2006**)[82].

However they frequently get larger as they proceed medially. Therefore, a sinus lift procedure over partial septa should proceed from lateral to medial; because elevation attempted from anterior to posterior is more prone to create a perforation.

**Maxillary Ostium:**

Ostium is the opening from the sinus to the middle meatus of nose. It is situated on the superior aspect of the medial wall of maxillary sinus above the first molar. The mean distance from the most inferior point of the antral floor to the ostium is 28.5mm (**Uchida Y 1998**)[85].

**Sinus Membrane:**

The normal width of Schneiderian membrane is generally 0.3 to 0.8 mm (**Mogensen 1977**)[49], however it can appear thicker if there is chronic inflammation resulting in hyperplasia.

The lining of the maxillary sinus is consistent with that of the other paranasal sinuses. **Sharaway** and **Misch (1999)**[47] suggested that the periosteal portion of this membrane is not similar to the periosteum covering the cortical plates of the maxillary or the mandibular residual ridges and jaws. The very minimal presence of osteoblasts may account for the enlargement of the

antrum after tooth loss. The sinus membrane also exhibits few elastic fibers making elevation from the bone relatively easy.

The perinasal sinuses are normally lined by a mucous membrane composed of either pseudo stratified, ciliated, cuboidal or columnar epithelium with goblet cells. Its thickness varies between 0.3 to 0.8 mm. The mucous material of the sinus in health has two layers: a top mucoid layer and a bottom serous layer. The top layer is sticky and collects bacteria or other debris (**Mogensen1977**)[49].The muco ciliary apparatus protects the sinus against infection by removing the organisms trapped in the mucus through the ostium. The membrane also acts as a biologic barrier, and an increased chance of infection results if the membrane perforates.

The maxillary sinus Ostium and the Infundibulum link the maxillary sinus with the middle meatus of nasal cavity. The infundibulum is a narrow passage representing the superomedial extension of the ostium and extends approximately 7 to 10 mm. These structures are referred to as the osteomeatal unit (**Bell 1976**)[6].

The physiologic functions of the paranasal sinuses include decreasing skull weight, providing resonance, improving olfaction, adding humidity to air to keep tissues in the nose, mouth and throat moist and also to regulate the intra nasal pressure.

The structures beneath the sinus consist of the alveolar ridge and the maxillary posterior teeth. The alveolar bone has an external cortex, an internal cortex in intimate contact with any teeth that are present, and a cortex beneath the sinus. Spongy bone is situated between the cortical plates. The loss of posterior maxillary teeth leads to bone loss because of osteoclastic activity that starts mainly from the sinus membrane but also, to a lesser extent, from the alveolar bone (**Davarpanah M 2001**)[15].

## MAXILLARY SINUS PNEUMATIZATION FOLLOWING EXTRACTION

Pneumatization is a physiologic process that occurs in all paranasal sinuses during the growth period, causing them to increase in volume (**Shea JJ 1936**)[68]. With the completion of eruption of the third molars, the pneumatization of the sinus ends and the sinus reaches 5mm inferior to the nasal floor.

Histologic examination has shown that the pneumatization process occurs by osteoclastic resorption of the cortical walls of the sinus and the layering of osteoid inferior to it (**Wehrbein 1992**)[92].

The rate and degree of the pneumatization process after tooth loss may be influenced by:

1. The protrusion of the tooth roots into the sinus cavity. Roots that protrude into the sinus have a thin cortical bone lining. During extraction this bone may break and dislocate, thus allowing the sinus to expand towards the empty socket.

2. Molar extraction- Greater pneumatization has been found after molar extraction in comparison to premolar extraction. The reason may be the large defect left in the alveolar bone after molar extraction, which requires a longer healing time, thus allowing the sinus to pneumatize (**Wehrbein 1992**)[92].

The decrease of functional force transferred to the bone after tooth loss causes a shift in the remodelling process towards bone resorption (**Misch 1999**)[47].

## CLASSIFICATION BASED ON RESIDUAL BONE HEIGHT

### Jensen OT (1998)[28]

| Class | Residual Bone Height ( RBH) mm | Recommended Procedure |
|---|---|---|
| A | ≥10mm | Classical Implant Placement |
| B | 7 to 9 mm | Osteotome Technique / Immediate Implant Placement |
| C | 4 to 6 mm | Lateral Window approach with immediate or delayed implant placement |
| D | 1 to 3 mm | Lateral Window and delayed implant placement |

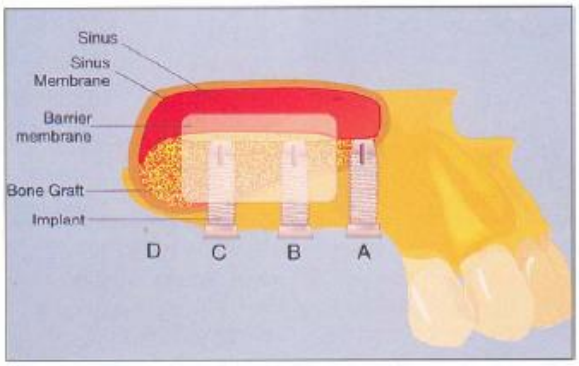



Fig 5-4 Site classification to aid in communication and treatment planning. Where less than 6 mm is present, the utility of a crestal approach is much diminished, and a lateral approach is better. Also, a class B or class A case is better for immediate placement situations, while a class CorD site is better suited to a delayed approach.

## ABC SINUS AUGMENTATION CLASSIFICATION

### Hom-Lay Wang & Katranji (2008)[25]

| Class | Location of Sinus floor from the crest of bone (mm) | Width (mm) | Distance from bone crest to adjacent CEJ (mm) | Recommended procedure |
|---|---|---|---|---|
| **Class A** (Abundant bone) | 10 | 5 or greater | 3 or less | Implant placement/immediate implant placement |
| **Class B** (Barely sufficient bone) | 6-9 | 5 | 3 or less | Osteotome/immediate implant placement |
| *Division H* (Horizontal defect) | 6-9 | Less than 5 | 3 or less | Osteotome and Ridge expansion GBR/Onlay graft/ immediate or delayed implant placement |
| *Division V* (Vertical defect) | 6-9 | Greater than or equal to 5 | More than 3 | GBR followed by Osteotome / delayed implant placement |
| *Division C* (Combined defect) | 6-9 | Less than 5 | More than 3 | GBR and/or Onlay graft followed by osteotome and delayed implant placement |
| **Class C** (Compromised Bone) | 5 or less | 5 or more | 3 or less | Lateral wall sinus elevation/immediate or delayed implant placement |
| *Division H* (Horizontal defect) | 5 or less | Less than 5 | 3 or less | Lateral wall sinus elevation & GBR/Onlay graft/ delayed implant placement |
| *Division V* (Vertical defect) | 5 or less | Greater than or equal to 5 | More than 3 | Lateral wall sinus elevation & GBR followed by Onlay graft (if indicated)/ delayed implant placement |
| *Division C* (Combined defect) | 5 or less | Less than 5 | More than 3 | Lateral wall sinus elevation & GBR followed by Onlay graft/ delayed implant placement |

## MAXILLARY SINUS AUGMENTATION TECHNIQUES

In the posterior maxilla, adequate bone volume is often unavailable because of severe post extraction alveolar crest resorption coupled with age-linked sinus pneumatization. Severe alveolar bone resorption occurs in long standing edentulous patients, especially if edentulism is preceded by untreated periodontal disease and often dictates the need for reconstructive osseous surgery to reestablish adequate bone volume for implant positioning (**Chanavaz 1990**)[12].

Currently, maxillary sinus grafting is a well established, reliable surgical procedure to increase bone volume in the posterior maxilla for implant placement. Dental implant placement associated with augmentation of the sinus floor in a severely atrophied maxilla can be performed in one or two surgical stages depending on the height of the residual alveolar bone. In a one-stage procedure, a minimum base height of 4 to 5mm is recommended for adequate implant stabilization and parallelism. A two-stage approach is performed when there is insufficient residual bone. This allows healing of the graft material for future implant sites (**Smiler DG 1992**)[70].

## LATERAL WINDOW APPROACH

The most widely used technique for maxillary sinus floor elevation is the classical lateral window technique introduced by Tatum in 1976. In this technique, access to the maxillary sinus is obtained by drilling a boney

window in the lateral sinus wall using a small round bur, while ensuring that the sinus membrane remains intact. The sinus membrane is then elevated, mobilized together with the attached boney window and rotated medially and then augmentation with autogenous bone and /or other grafting material is carried out. This procedure provided increased bone volume and height to aid in primary stabilization of one or more endosseous implants (**Tatum 1986**)[80].

**Disadvantages with lateral window technique:**

The lateral window sinus lift remains a technique sensitive procedure due to the high risk of schneiderian membrane perforation and hemorrhagic complications, the latter of which is associated with the inadvertent laceration of the intraosseous arterial supply to this region (**Solar 1999**)[71].

**OSTEOTOME TECHNIQUE**

**Summers et al (1994)**[75] developed a surgical technique using osteotomes which is indicated when the residual bone height from the sinus floor is 5 to 6 mm and the bone is of low density. Bone is compacted laterally and apically around the implant site by using osteotomes of progressively increasing diameter. To increase the amount of bone gain, the use of grafting materials is proposed, with or without the use of autogenous bone. A success rate of 96% over 0 to 5 years was reported with 143 implants placed in 46 patients. Later, a modification of this technique was introduced Bone Added Osteotome Sinus Floor Elevation (BAOSFE).

**Coatoam and Krieger et al (1997)**[13] used methods similar to the osteotome technique. Their method used demineralised lyophilized bone, with or without autogenous bone. Implants were placed at the same surgical visit. The authors obtained 92% success for 89 implants that were followed up for 6 to 42 months.

**Zitzmann and Scharer et al (1998)**[99] reported the results of three different methods of sub sinus grafts and placement of implants: two-stage appositional, one –stage appositional, and osteotome technique. 59 implants were placed in 20 patients using the osteotome technique. A success rate of 95% [three failures] was reported after a mean follow –up period of 6 to 24 months. A radiographic gain of 3.5 mm was obtained with the osteotome technique. These authors considered that this technique is contraindicated where there is a bone height of less than 6mm.

**Davarpanah et al (2001)**[15] proposed a modified osteotome technique, in which the bone thickness below the sinus was ≥ 5mm. This technique was based on the use of a combination of osteotomes, drills, and screw –type implants with a rough surface texture. A resorbable graft material was introduced into the surgical site before using the first osteotome. This material served as a shock absorber to gently fracture the sinus floor. With each use of the osteotome to condense the material, the sinus membrane is lifted approximately by 1mm.

**Toffler et al (2004)**[83] evaluated the success of osteotome mediated sinus floor elevation (OMSFE) using autogenous and xenogenic bone and a variety of screw type implants in 276 sites. The mean residual bone height was 7.1mm. The mean increase in bone height of the implant site using OMSFE was 3.8mm. He concluded that OMFSE can be used predictably for implant placement at sites with moderate vertical deficiencies in the posterior maxilla.

**Luciano Malchiodi et al (2011)**[37] described Osteotomes with two types of working extremities: concave and convex. The concave spike mainly cuts, while the convex end deals with compression. The alternating use of concave and convex ends allows two different vectors of osteocompression. The first is directed apically while the latter is directed length wise. The concave osteotomes are sharp at the apex and transmit their dislocating force vertically. The convex osteocompressors displace the force laterally that tend to create resistance at the apex. The author has concluded that; when unexpected bone deficiency with vestibular collapse occurs, the use of these osteotomes can restore the emerging profile of the future prosthetic manufactured product, through cortical transversal widening and spongious bone compacting.

**Disadvantages with Osteotome Technique :**

- The chances of achieving a sufficiently high elevation with the osteotome technique are limited (**Zitzmann NU 1998**)[99].

- **Vernamonte et al (2011)**[91] reported that OSFE leads to complications, which involve local problems such as tearing of the sinus membrane, infection, bleeding, sinusitis and benign paroxysmal positional vertigo (BPPV).

- The action of osteotomes can hardly be controlled during the application of malleting pressure resulting in an unwanted penetration of the instruments and/or graft into the sinus cavity.

- According to standard protocol, the osteotome technique cannot be used to elevate the sinus membrane more than 5 to 6mm (**Rodoni 2005**)[62].

- **Rosario Sentineri et al (2011)**[65] suggested to avoid the usage of osteotomes, if the force required was greater than 20 MPa, so as not to cause tissue damage from excessive compression.

**OTHER TECHNIQUES FOR SINUS AUGMENTATION**

**Trombelli et al (2010)**[84] proposed the smart-lift technique characterized by transcrestal approach by means of specifically designed instruments with adjustable stop devices. 14 implants were placed in 11 patients using the proposed technique. The augmented sites had a pre surgical residual bone height of 6.1 mm whereas the mean length of the implants inserted in the augmented sites was 10.3±0.9mm. No complications were observed during or after the surgical procedure. Six months after, a newly

formed mineralized tissue was found at or beyond the level of the implant apex in all cases. He concluded that this technique represents a suitable option to elevate the sinus floor with a limited post operative morbidity.

**Roni Kolerman et al (2011)[64]** evaluated the long term outcome of crestal core elevation (CCE) procedure over a period of 11 years. Extraction sites were drilled with calibrated trephine bur to a distance of 1 mm from the sinus membrane. The trephined interradicular bone and the sinus membrane were imploded into the sinus. Then the crater was filled with deproteinised bovine bone mineral or FDBA. Implants were placed after 4 months. Results confirmed that the procedure had a success rate of 68.9%. He concluded that CCE implemented with molar extraction provided therapeutic benefits and the subsequent implant placement revealed excellent survival rate.

**Sinus floor elevation using Piezoelectric Surgery:**

The piezoelectric device with an ultrasonic vibration of 25 to 30 KHz, precisely cuts only mineralized structures without cutting soft tissues which remain undamaged even in case of accidental contact. The movement of piezosurgical knife is very small, so the cutting precision is greater and causes less discomfort for the patient (**Vercellotti 2006**)[90].

**Baldi D et al (2011)[4]** reported that Piezosurgery for sinus floor augmentation using a one step crestal approach, where the residual bone is ≤ 7.5mm and installation of tapered implants yielded the best results.

## MINIMALLY INVASIVE ANTRAL MEMBRANE BALLOON ELEVATION (MIAMBE) TECHNIQUE

**Soltan et al (2005)**[72] reported antral membrane balloon elevation via a lateral bone fenestration in 4 patients with alveolar crest height of 4 to 6mm. Augmentation was done using allograft mixed with PRP. The author concluded that the procedure was highly successful and predictable and likely to reduce pain, bleeding, infection and other morbid symptoms often associated with other sinus lift procedures.

**Kfir E et al (2007)**[32] utilized a non commercial prototype MIAMBE device which was screwed upto 0.5mm superior to the sinus floor, after the preparation of implant osteotomy using sequential osteotomes (3.1mm). Once the desired inflation and the sinus floor elevation were obtained, the balloon was deflated. A mixture of autologous fibrin, bone particles and synthetic bone speckles were injected with a dedicated syringe under the elevated antral membrane. After bone transplantation, implants were placed. The author concluded that the procedure yielded satisfactory bone augmentation and also eliminated the complications and discomfort associated with lateral window technique.

**Kfir E et al (2009)**[33] presented the results of 26 consecutive patients with septated maxillary sinus who underwent MIAMBE followed by bone augmentation and implant fixation. 24 patients had completed the procedure successfully with implant survival of 95.2% observed at 6 to 9 months. He

concluded that MIAMBE can be used as an alternative to currently employed methods of maxillary sinus augmentation especially in the presence of septated maxillae.

**Xiulian Hu et al (2009)**[94] assessed the efficacy and safety of MIAMBE followed by bone grafting and implant placement in 28 patients with a single tooth missing in the posterior maxilla. He concluded that MIAMBE can be used as a predictable alternative to the invasive sinus augmentation procedures which are currently in use.

## MATERIALS USED FOR SINUS AUGMENTATION

### AUTOGENOUS BONE GRAFTS

Autogenous bone grafts are considered the gold standard for bone regeneration procedures. Commonly procured from the iliac crest, tibia, mandible, or skull, the advantages of autogenous bone include, availability of sufficient volume of material, angiogenic proliferation, biologic safety, presence of vital osteogenic cells and release of growth factors. The disadvantages of host-procured bone are increased blood loss, donor site morbidity, increased instance of infection, and patient refusal (**Marx 1993**)[39].

Autogenous bone grafts have been reported to have a history of greater than average resorption, leading to subsequent sinus repneumatization and / or implant failure (**Garg AK 2001**)[19].

**Browaeys H et al (2007)**[8] suggested that autogenous bone is the most predictable material of choice for augmentation procedures, despite a 40% resorption, because it is highly osteoconductive and less dependent on sinus floor endosteal bone migration. The addition of bovine bone mineral to autogenous bone can be beneficial for graft success because it acts as a slowly resorbing space maintainer. Porous hydroxyapatite is suitable when mixed with autogenous bone because it enhances bone formation and bone-to-implant contact in augmented sinuses. Histological evaluation showed that demineralized freeze dried bone is inferior to other materials.

A wide variety of bone replacement grafts have been used in the sinus lift procedure to avoid the drawbacks inherent with the autogenous grafts. These include allografts, xenografts and alloplasts (**Wheeler 1996**)[93].

**XENOGRAFTS**

**Yong-Moo lee et al (2006)**[95] examined the sequential progress of healing at two different time intervals, following delayed sinus augmentation using bovine hydroxyl apatite (BHA) as the sole grafting material. 14 pairs of bone biopsies were taken from 10 patients after 6 and 12 months of healing respectively. The average proportion of newly formed bone was 18.3% at 6 months and 26.6% at 12 months. The study concluded that implant placement in 100% BHA in sinus augmentation had predictable integration. Histologically newly formed bone following sinus augmentation with BHA had increased in volume and matured over 12 months period.

**Ferreira et al (2009)**[16] evaluated the use of anorganic bovine bone (ABB) associated with a collagen membrane for sinus augmentation. 406 sinus augmentations were carried out with 100% anorganic bovine bone (ABB) along with a collagen membrane (CM), in cases with bone availability $\leq$ 7mm. The author concluded that the implants placed in these grafted sinuses had an excellent and predictable survival rate of 98%.

**Zerbo et al (2004)**[97] examined the use of a porous $\beta$ – TCP in a split mouth model for sinus floor augmentation. Five patients were treated

bilaterally, receiving 1-2mm sized β – TCP particles (Cerasorb®) on one side and autologous chin bone particles on the other side. The average bone volume formed in the augmented sinus at the control site was 41% and 17% in the test side. Osteoid formation tended to be higher in test side biopsies (1.3%) than in the controls (0.3%), indicating ongoing bone formation in the TCP material. The histological results indicated that β – TCP is an acceptable bone substitute material for augmentation of the maxillary sinus.

**Renzo Guarnieri et al (2006)**[59] evaluated the radiographic and histologic results when granular medical grade calcium sulfate hemihydrate (Surgiplaster Sinus) was used as a grafting material in 15 sinus augmentation procedures. He concluded that MGCSH led to appropriate osseointegration of dental implants and can be used to create adequate bone volume before implant placement.

**ALLOGRAFTS**

Allograft is generally used in one of the two following forms:

- Freeze-dried bone allograft (FDBA) and
- Demineralized freeze-dried bone allograft (DFDBA).

These two types of graft materials work by different mechanisms. FDBA provides an osteoconductive scaffold and elicits resorption when implanted in mesenchymal tissues (**Goldring SR 1988**)[23]. DFDBA also

provides an osteoconductive surface. In addition, it provides a source of osteoinductive factors (**Urist MR 1965**)[86]. Therefore, it elicits mesenchymal cell migration, attachment, and osteogenesis when implanted in well-vascularized bone.

Freeze dried bone allograft (FDBA) and demineralised freeze dried bone allograft (DFDBA) are both harvested from cadaverous sources in the same manner, with the difference being that DFDBA undergoes additional step of decalcification (**Mellonig 1991**)[42]. Exposure of BMP by demineralization of the allograft material is thought to enhance the osteogenic potential of the graft material (**Urist 1971**)[87].

The AATB (American Association of Tissue Banks 1998) advocates excluding collection of bone under the following circumstances:

1. Donors from high-risk groups, as determined by medical testing and/or behavioral risk assessments.
2. Donor tests positive for HIV antibody by ELISA.
3. Autopsy of donor reveals occult disease.
4. Donor bone tests positive for bacterial contamination.
5. Donor tests positive for hepatitis B surface antigen (HBsAg) or hepatitis C virus (HCV).
6. Donor tests positive for syphilis.

**Tatum et al (1993)**[81] evaluated the efficacy of irradiated allogenic cancellous bone and marrow (RMTB) in sinus augmentation procedure. He concluded that among all available allograft, irradiated bone is most similar to autogenous bone in terms of demonstrating rapid replacement and consistent establishment of a reasonable ratio of new bone with less expense and morbidity than that associated with autogenous material.

**Nishibori et al (1994)**[52] evaluated the healing of DFDBA and autogenous iliac bone graft after sinus augmentation. Bone cores were obtained with a trephine bur from the grafted regions at the time of implant placement. The results of the study suggested that the autogenous graft produced adequate quantity and quality of bone for implant placement, whereas DFDBA grafts were not completely remodeled by the host and produced bone of insufficient quality and quantity.

**Jensen J et al (1994)**[27] evaluated the use of irradiated cancellous bone allograft in sinus augmentation procedure followed by immediate implant placement. Histologic analysis of trephined bone cores obtained 6 months after implantation demonstrated the presence of significant amount of mineralized bone. Results confirmed that Irradiated mineralized cancellous bone allograft could be used successfully in combination with an expanded polytetrafluoroethylene membrane. However cancellous bone contains no BMP and the amount of radiation required to sterilize mineralized allograft

may destroy the remaining bone matrix, thereby altering the osteoinductive property of the graft (**Ripamonti 1989**)[61].

**Cammack GV et al (2005)[9]** quantified new bone formation from biopsies of DFDBA and FDBA following sinus and ridge augmentation procedures in 93 patients, during implant placement. Results showed no significant difference between the percentage of new bone formation by either FDBA (41.8%) or DFDBA (41.7%).

**Ricardo Gapski et al (2006)[60]** made a histologic analysis of solvent preserved human mineralized bone allograft in sinus elevation procedure. During solvent preservation, the mineral and collagen appears to remain intact, thus facilitating bony ingrowth. Results revealed that the grafted sites formed 73.3% of new bone and the bone density was similar to that of the host bone. The author concluded that human mineralized bone allograft can be successfully used in sinus augmentation procedures.

**Stuart J Froum et al (2006)[74]** histomorphometrically evaluated the vital bone formed using 2 different materials: Puros, a mineralized cancellous bone allograft (MCBA) and Bio-oss, an anorganic bovine bone matrix (ABBM) in thirteen patients who required bilateral sinus augmentation. Histomorphometric analysis of 10 MCBA cores and 9 ABBM cores revealed average vital bone content of 28.25% and 12.44%, respectively, at 26 to 32 weeks following graft placement. Study concluded that a higher average

percentage of new vital bone was seen around MCBA particles than ABBM particles.

**Roni kolerman et al (2008)[63]** evaluated (both histologically and histometrically) the newly formed bone after sinus augmentation using ground cortical bone allograft (FDBA) and internal collagen membrane in 23 sites. Implants were placed after 9 months of sinus augmentation. Results revealed a mean of 29.1% of newly formed bone, 51.9% of connective tissue and 19% of residual graft material. He concluded that FDBA is bio compatible and osteo-conductive when used primarily in maxillary sinus augmentation procedures and it may be used safely without interfering with the normal reparative bone process.

**Gavriel Chaushu et al (2009)[21]** assessed the survival rate of implants placed during sinus augmentation and stabilized by the use of cancellous freeze dried block allograft in 28 patients with RBH less than 4mm. Results revealed that the overall success rate of implants placed was 94.4%. Vertical augmented bone within the sinus ranged from11 to 14 mm. The Histologic evaluation showed newly formed bone containing viable osteocytes merged with residual graft bone, characterized by empty lacunae, devoid of osteocytes. Author concluded that cancellous block allograft seems to possess potential as a grafting material for sinus floor augmentation with simultaneous implant placement.

## MECHANISM OF ACTION OF BONE SUBSTITUTES

Bone grafts can cause bone replacement through three different mechanisms: osteogenesis, osteoinduction and osteoconduction (**Misch and Dietsh 1993**)[46]. Osteogenesis refers to organic material capable of forming bone, directly from osteoblast. An osteogenic graft can therefore said to be derived from, or composed of tissues involved in the natural growth or repair of bone. It is for this reason that they can encourage or activate more rapid bone growth in defective sites (**Garg 2004**)[20].

Osteoinductive materials are capable of inducing the transformation of undifferentiated mesenchymal cells into osteoblasts or chondroblasts and enhance bone growth or even grow bone where it is not expected (**Misch and Dietsh 1993**)[46]. **Urist et al (1980)**[88] recognized the mechanism as dependent upon many factors which includes specific proteins (BMP) located primarily in the cortical bone.

Osteoconduction is characteristic of a material (often organic) which permits bone apposition from existing bone and requires the presence of bone or differentiated mesenchymal cells (**Rejda 1977**)[58]. Osteoconduction provides a physical matrix or scaffolding suitable for the deposition of new bone. Osteoconductive graft are conductive to bone growth and allows bone apposition from existing bone, but do not produce bone formation themselves when placed within soft tissue (**Garg 2004**)[20]. The healing of dental implants

with a direct bone contact has been described as an osteoconductive process (**Albrektsson 1985**)[3].

## RADIOGRAPHIC EVALUATION OF SINUS AUGMENTATION

**Akesson et al (1989)**[2] stated that a well taken panoramic radiograph can provide information on the bone surrounding the teeth or implants and bone height measurements.

Panoramic radiographs contain valuable information about the anatomy of the maxillary sinus, implants and graft material, however panoramic radiographs taken with a non standardized technique results in a wide range of magnification error and distortions (**Reddy 1994**)[57]. The panoramic radiograph offers the interpreter, a two-dimensional view of a three dimensional object. Therefore, panoramic radiographs can only be used for bone height measurements and do not allow for volume measurements.

**Nicolaas et al (2001)**[51] made a retrospective radiographic analysis of sinus graft and implant placement procedures over 3 years. Using Periovision software, the region of interest in the panoramic radiograph was grabbed and digitized. The height of the bone was measured and calculated with the use of a conversion factor that adjusted for magnification error. He concluded that high-quality panoramic radiographs provided relatively repeatable geometry.

**CT evaluation in Sinus augmentation:**

Computed tomography (CT) provides a more accurate visualization of anatomical structures without super-imposition and allows for a continuous view of surface topography while preserving the soft tissue detail. It has been reported that the thickness and width of the alveolar bone and the process of new bone formation could be better assessed with sagital and axial images from CT than with a panoramic radiographic image when planning surgery (**Szabo 2001**)[79].

**Lecomber AR et al (2001)**[34] compared the radiation doses from imaging protocols for dental implant planning either using conventional radiography only (dental panoramic radiography (DPR), cephalometry or involving computed tomography (CT). Organ absorbed, and effective doses were calculated. Results showed E (exc) {excludes the salivary tissue from the remainder organs (designated E (exc)}, for panoramic, cephalometric and cross-sectional tomography using DPR was 0.004 mSv, 0.002 mSv and 0.002 mSv, respectively, whereas with CT it was 0.314 mSv. The author concluded that E (Inc) greatly increases the apparent radiation burden, especially with high dose procedures. CT techniques can provide excellent images, but at the cost of increased radiation detriment. DPR with a cross-sectional tomography facility may give adequate clinical information at a greatly reduced dose.

# STUDY DESIGN

## Patient Selection

The study included a total of 9 patients (10 sites), 8 males and 1 female, aged between 25 to 60 yrs who were referred to the Department of Periodontics, Ragas Dental College and Hospital, Chennai for implant placement in the edentulous posterior maxilla. Informed written consent to participate in this study was obtained from all patients, in particular explaining the objectives and protocol of the study, and possible side effects.

## Inclusion Criteria

Patients were selected using the following criteria:

1. With a unilateral or bilateral loss of teeth in the maxillary pre-molar or molar area.
2. Crestal bone height greater than 5mm below the sinus floor as determined by an OPG.
3. Patients with Class B, division – V (Vertical Defect) were included (ABC classification by **Hom-Lay Wang 2008**)[25].
    a. The bone crest is 6 to 9mm from the sinus floor.
    b. The bone width is 5mm or more.
    c. The bone crest is more than 3mm from the adjacent CEJ.

4. Patients with good oral hygiene and without any active periodontal disease were selected.

**Exclusion Criteria**

1. Systemic conditions such as uncontrolled Diabetes Mellitus, Hypertension or any other contra-indicating systemic complications.
2. Patients with Immune suppression and bleeding disorders.
3. Patients with Oro-facial cancer, chemotherapy or head and neck radiotherapy twelve months prior to the surgery.
4. Any pathological lesion in the sinus (benign or malignant tumor, mucocele or active sinusitis).
5. Untreated active periodontitis in neighboring teeth.
6. Patients with long term steroid therapy or bisphosphonate medication.
7. Patients who are not current smokers.
8. Pregnant women and nursing mothers.
9. Any previous history of sinus surgery.
10. Patients with any drug abuse including alcohol.

**Pre Operative Diagnostic Evaluation**

**Clinical Examination**

At the initial visit, all patients underwent a clinical and occlusal examination. An oral hygiene assessment of the patient was performed. Periodontal health status was assessed for the neighboring teeth on either side of the edentulous ridge.

The edentulous area in the posterior maxilla was examined and the ridge width and mesio-distal diameter were measured. Patients who had an adequate ridge width were further evaluated radiographically, for the availability of crestal bone height.

**Radiographic examination**

Pre procedural panoramic radiographs were used to assess the vertical bone height (VBH) below the sinus lining. Digital Periapical radiographs were taken before the procedure was initiated.

Evaluation of VBH from the alveolar crest (arbitrary horizontal line joining the CEJ of the adjacent teeth) to the floor of the sinus, was done using OPG. The following three points were marked on the arbitrary horizontal line joining the CEJ.

- Point A- 2mm from the mesial tooth.
- Point B- Midpoint from the line joining point A & C.

- Point C- 2mm from the distal tooth.

From these 3 points mentioned above, vertical arbitrary lines were drawn to the floor of the maxillary sinus and the values were recorded.

**Pre-Operative Casts and Bone Mapping**

An impression of the maxillary arch was made using hydrocolloid impression material and cast was obtained. Bone mapping was done to determine the width of the alveolar ridge.

# ARMAMENTARIUM

## DIAGNOSTIC INSTRUMENTS

1. Mouth mirrors
2. Graduated William's probe.
3. Tweezers
4. Metal ball stent

## SURGICAL INSTRUMENTS

1. 2ml disposable syringe (Unolock)
2. 2% Lignocaine hydrochloride with 1:80,000 adrenaline.
3. Bard parker handle No.3
4. Bard parker blade No.15
5. Periosteal elevator (Goldmann fox)
6. Austin cheek retractor
7. Curved Goldmann fox scissors
8. Needle holder
9. Suture cutting scissor
10. Tissue forceps

11. Kidney tray
12. Stainless steel bowl-2
13. 3-0 Silk suture
14. 20ml saline (irrigation) syringes
15. Normal physiological saline (0.9%W/V)
16. Round surgical bur
17. Pilot drill bur (2.0mm)
18. Contra angle hand piece
19. Metal suction tip
20. Bone graft carrier
21. Osteotomes (3.8mm to 5mm)-Bone expanders
22. Osteotomes-Bone condensers
23. Mallet
24. Povidine-iodine solution
25. Physio - dispenser with internal irrigation system

26. **Sinus-lift balloon system (Zimmer dental)** comprising:

    a. 5ml syringe,

    b. Polyvinyl chloride (PVC) tubing,

    c. Metal shaft with the tip connected to a latex mini balloon.

27. Bone graft (Rocky Mountain Tissue Bank, Denver, Co)

**Sinus-lift balloon system**

The Sinus-lift balloon system (Zimmer Dental) was developed to gently elevate the Schneiderian membrane with minimal trauma and without the use of sharp instruments.

The apparatus is a pneumatic device consisting of a 5ml syringe, polyvinyl chloride (PVC) tubing and a metal shaft with the tip connected to a latex mini balloon with an inflation capacity of approximately $5cm^3$.

The amount of saline placed in the syringe was determined by the number of millimeters the sinus membrane would need to be elevated – 1cc of saline solution corresponds to 6mm (+/- 0.5mm) of membrane elevation.

**Bone graft**

Irradiated allogenic cancellous bone and marrow particulate (Rocky Mountain Tissue Bank, Denver, Co) randomly sized between 2 to 3mm has been used as a bone substitute for sinus augmentation in this study. RMTB grafts are "Donated Human Tissue" which has been prepared from a donor that has met the donor suitability criteria under American Association of Tissue Banks standards (1998). All donors have been screened and shown negative for the presence of any active infectious disease, malignancies, degenerative neurological disease and diseases of unknown etiology. It is a trabecular allograft obtained from the spinal column and treated with 2.5 and 3.8 megarads of radiation.

## SURGICAL TECHNIQUE

All patients were subjected to prophylactic antibiotic coverage (Amoxicillin 2gms) 2 hours, prior to sinus floor augmentation procedure. They were made to rinse their mouth with 0.2% chlorhexidine gluconate for 2 minutes, prior to surgery. The face and surgical site were wiped with Povidine Iodine (Betadine) solution.

Local anesthesia (2% Lignocaine with 1:80,000 adrenaline) was administered to the patient. Posterior and middle superior alveolar nerve block along with greater palatine nerve block was given to ensure complete anesthesia of the surgical site.

Immediately prior to surgery, the balloon (sinus-lift balloon system, Zimmer Dental) was twice inflated with air and then deflated to achieve preliminary stretching.

An alveolar mid-crestal horizontal incision was performed in the edentulous site and connected with the sulcular incision of adjacent teeth. Muco-periosteal flap was elevated exposing alveolar crest of the bone. No vertical releasing incision was employed and the flap was reflected not exceeding the alveolar ridge.

Cortical perforation was done using a round bur, followed by the pilot drill of 2mm and 2.8mm reaching about 1mm short of the sinus floor. After radiographic verification of the sinus floor with the digital periapical

radiographs, sequential expansion of the osteotomy site was achieved using a series of osteotomes (from 3.8mm to 5mm) in graduated diameters, to laterally condense the low density maxillary bone. Care was taken to gently penetrate the sinus floor and slightly elevate the schneiderian membrane to allow 3mm of access for the deflated balloon.

After examining the integrity of sinus membrane by Valsalva maneuver; the sinus lift balloon was anchored and secured into the osteotomy site. Then the balloon was slowly inflated with gentle inflating pressure with normal saline (1cc of saline solution corresponds to 6mm of membrane elevation). Digital periapical radiographs were taken to assess the balloon inflation and the extent of sinus floor elevation at the surgical site during the procedure.

Once the desired elevation (usually greater than 10mm) was obtained, the balloon was deflated. A second test of membrane integrity was done by Valsalva maneuver. Irradiated allogenic cancellous bone and marrow (RMTB) was filled under the elevated sinus membrane using bone condensers.

After the sinus floor augmentation procedure was completed, the muco-periosteal flap was repositioned and closed with simple interrupted sutures, using 3-0 silk suture material.

**Post Operative Instructions**

Patients were instructed to refrain from blowing their nose for 2 weeks to prevent increased pressure in the operated sinus. They were also instructed to avoid sneezing or coughing, just to ensure that the surgical site remained undisturbed during the initial stages of healing. Patients were instructed to avoid wearing their removable prosthesis and were advised to follow a soft diet.

Systemic antibiotic therapy comprised of Amoxycillin, 500 mg three times per day for 5 days after surgery. Anti-inflammatory analgesics (Ibuprofen) 400mg three times a day was prescribed for 5 days. The patients were instructed to rinse twice daily with 0.2% chlorhexidine gluconate mouth rinse for 2 weeks.

Patients were examined after a week and suture removal was done. The grafted sinus was allowed to heal for 6 months.

**Post Operative Radiographic Evaluation**

During the 3 months and 6 months follow up period, radiographic assessment of the vertical bone gain in the augmented sites was done using OPG at the three reference points (A, B, C).

# PROFORMA

PATIENT NAME : DATE:

OP NUMBER :

AGE/SEX :

ADDRESS :

CONTACT NUMBER :

MARITAL STATUS :

OCCUPATION :

CHIEF COMPLAINT :

H/O PRESENTING ILLNESS: :

MEDICAL HISTORY :

PAST DENTAL HISTORY :

HABITS :

FAMILY HISTORY :

## CLINICAL EXAMINATION

EXTRA ORAL :

INTRA ORAL :

HARD TISSUE EXAMINATION :

MISSING TOOTH :

## BLOOD INVESTIGATIONS

Bleeding time :

Clotting time :

WBC-total count :

WBC –differential count :

Haemoglobin % :

Random Blood Sugar :

## RADIOGRAPHS

OPG

RVG (at the time of surgery)

## MEASUREMENT USING OPG

| Vertical height of the bone | Pre - operative | Immediate Post - operative | Post – operative 3 months | Post- operative 6 months |
|---|---|---|---|---|
| **A** | | | | |
| **B** | | | | |
| **C** | | | | |

**INFORMED PATIENT CONSENT**

**DEPARTMENT OF PERIODONTICS**

**RAGAS DENTAL COLLEGE AND HOSPITAL,**

**UTHANDI, CHENNAI -119.**

PATIENT NAME :

AGE / SEX :

I have been informed that I need to undergo sinus elevation procedure before implant placement. I have no objection for undergoing the treatment and if the treatment shows no anticipated results, I agree to undergo suitable /alternative method for the same. I give my consent for photographs and radiographs to be taken at the beginning, during, and end of the study.

I understand that I am free to withdraw my consent without any effect to my treatment.

STATION :

DATE :

SIGNATURE OF THE PATIENT :

SIGNATURE OF THE OPERATOR :

SIGNATURE OF THE HOD/GUIDE :

# RESULTS

A total of 10 sinus augmentation procedure was performed in 9 patients (one patient underwent bilateral sinus augmentation), utilizing the Sinus lift balloon system (Zimmer Dental) and Irradiated Cancellous Bone Allograft (RMTB). Each site is considered as a single patient for statistical purpose. Among the 10 patients; 9 patients completed a 3 months follow-up, but only 6 patients completed a 6 months follow-up period. The tenth patient was excluded from the study, as the follow-up period was less than 3 months.

The outcome of the graft placed during the procedure and the vertical bone gain achieved were investigated by means of panoramic radiographs, at the baseline and at the 3 months, 6 months follow-up period.

The radiographic examination after 3 months and 6 months showed radiopacity, suggesting the presence of dense homogenous bony mass, obtained as a result of the sinus augmentation procedure.

The following three points were taken as reference:

**Point A**: 2mm from the mesial tooth

**Point B**: Midpoint from the line joining point A and C

**Point C**: 2mm from the distal tooth

Clinically, no complications were observed during the surgical procedures. All patients healed uneventfully with no signs and symptoms of

maxillary sinus pathology, observed during the six months follow up period. The radiographic measurement of the vertical bone height of each patient is represented in Table 1 to 9.

## STATISTICAL ANALYSIS

The Mean and Standard Deviation of the radiographic measurement of the vertical bone height at the 3 reference points (A, B & C) were analyzed using SPSS version 12.0 software.

The paired **t** Test was adopted to evaluate the significance of differences in the mean bone height (MBH)

1. Between the pre-operative and post-operative (3 months) data where n=9 (Table No-10)
2. Between the pre-operative and post-operative (6months) data where n=6 (Table No-11)

**Interpretation of results:**

**Comparison of pre operative & post operative (3 months) mean bone height at 3 reference points (A, B, C) using OPG: (n=9)**

A).*Mean bone height measurement at point A:*

The mean bone height, pre-operatively at the point A was 8.6mm. At 3 months post-operatively it was 10.9mm. The mean increase in bone height was 2.3mm, which was statistically significant (p-0.002)**.

B). *Mean bone height measurement at point B:*

The mean bone height, pre-operatively at the point B was 6.5mm. At 3 months post-operatively it was 9.7mm. The mean increase in bone height was 3.2mm, which was statistically significant (p-0.002)**.

C). *Mean bone height measurement at point C:*

The mean bone height, pre-operatively at the point C was 8.5mm. At 3 months post-operatively it was 10.3mm. The mean increase in bone height was 1.8mm, which was statistically significant (p-0.02)*.

**Comparison of pre operative & post operative (6 months) mean bone height at 3 reference points (A, B, C) using OPG: (n=6)**

A).*Mean bone height measurement at point A:*

There was a relatable increase in MBH of 2.7mm during the six month follow up period, where the MBH at the baseline and post operative(6 months) was 8mm and 10.7mm respectively.

B).*Mean bone height measurement at point B:*

The mean bone height, pre-operatively at the point B was 6.16mm. At 6 months post-operatively it was 9.5mm, where there was a consistent increase of 3.34mm in MBH.

C).*Mean bone height measurement at point C:*

The mean bone height, pre-operatively at the point C was 7.75mm. At 6 months post-operatively it was 9.75mm, where there was a consistent increase of 2mm in MBH.

**MEASUREMENT OF VERTICAL BONE HEIGHT AT 3 REFERENCE POINTS (A, B, C) USING OPG**:

**Table No: 1** -Case 1

| POINT | Pre-operative(mm) | Post-operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 10 | 12 | 12.5 |
| B | 8 | 13 | 16.5 |
| C | 11 | 13.5 | 14 |

**Table No: 2**-Case 2

| POINT | Pre-operative(mm) | Post-operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 12 | 13 | 13.5 |
| B | 5 | 10.5 | 11 |
| C | 3.5 | 8 | 9 |

**Table No: 3-** Case 3

| POINT | Pre-operative(mm) | Post-operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 6.5 | 7 | 6.5 |
| B | 6 | 7.5 | 7.5 |
| C | 8.5 | 9 | 10 |

**Table No: 4**- Case4

| POINT | Pre-operative(mm) | Post - operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 5.5 | 9 | 10 |
| B | 6 | 9 | 8 |
| C | 8.5 | 11 | 10 |

**Table No: 5**- Case 5

| POINT | Pre-operative(mm) | Post - operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 7 | 9 | 7 |
| B | 6 | 7.5 | 6 |
| C | 5 | 7.5 | 5.5 |

**Table No: 6**- Case 6

| POINT | Pre-operative(mm) | Post- operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 7 | 11.5 | 15 |
| B | 6 | 6 | 8 |
| C | 10 | 8 | 10 |

**Table No: 7**- Case 7

| POINT | Pre-operative(mm) | Post - operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 9 | 12 | |
| B | 8 | 11.5 | |
| C | 7 | 10 | |

**Table No: 8**- Case 8

| POINT | Pre-operative(mm) | Post - operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 10 | 14 | |
| B | 8 | 11 | |
| C | 12 | 14 | |

***Table No: 9***- Case 9

| POINT | Pre-operative(mm) | Post operative(mm) 3months | Post-operative(mm) 6months |
|---|---|---|---|
| A | 10.5 | 11 | |
| B | 5.5 | 12 | |
| C | 11.5 | 12 | |

**COMPARISON OF PRE OPERATIVE & POST OPERATIVE (3 MONTHS) MEAN BONE HEIGHT AT 3 REFERENCE POINTS USING OPG – PAIRED t TEST.**

***Table No: 10***

| Point | Pre-Operative | | | Post – Operative 3 Months | | | P-Value |
|---|---|---|---|---|---|---|---|
| | n | Mean | SD | n | Mean | SD | |
| A | 9 | 8.6 | 2.1 | 9 | 10.9 | 2.21 | 0.002** |
| B | 9 | 6.5 | 1.17 | 9 | 9.7 | 2.38 | 0.002** |
| C | 9 | 8.5 | 2.94 | 9 | 10.3 | 2.43 | 0.02* |

**COMPARISON OF PRE OPERATIVE & POST OPERATIVE (6 MONTHS) MEAN BONE HEIGHT AT 3 REFERENCE POINTS USING OPG – PAIRED t TEST.**

***Table No: 11***

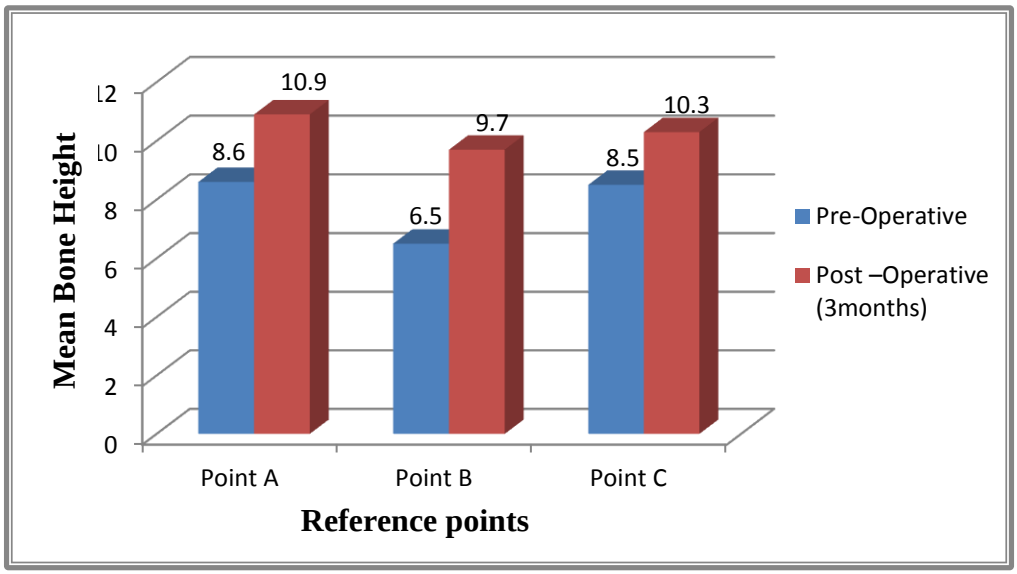
| Point | Pre-Operative | | | Post – Operative 6 Months | | | P-Value |
|---|---|---|---|---|---|---|---|
| | n | Mean | SD | n | Mean | SD | |
| A | 6 | 8 | 2.46 | 6 | 10.7 | 3.50 | 0.080 NS |
| B | 6 | 6.16 | 0.98 | 6 | 9.5 | 3.79 | 0.052 NS |
| C | 6 | 7.75 | 2.9 | 6 | 9.7 | 2.7 | 0.058 NS |

*denotes significance at 5% level

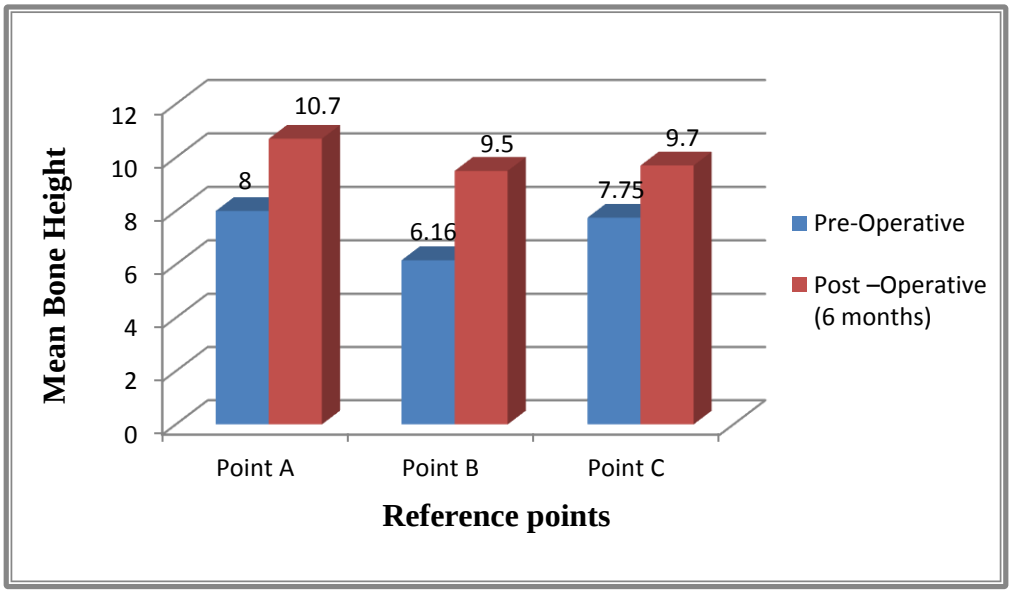
**denotes significance at 1% level

NS denotes- not significant

***Graph No 1: Comparison of Pre-Operative and Post-Operative (3Months) Mean Bone Height (MBH) using OPG***




***Graph No 2: Comparison of Pre-Operative and Post-Operative (6Months) Mean Bone Height (MBH) using OPG***



# DISCUSSION

Rehabilitation of the edentulous posterior maxilla with dental implants can be difficult because of insufficient bone volume caused by pneumatization of the maxillary sinus and crestal bone resorption.[66]

The efficacy of sinus augmentation therapy to increase bone volume in the maxillary posterior region has been well documented through animal and human histologic evaluations. Implant success rates in the sinus augmented areas are comparable to the success rates of implants placed in the non-augmented bone.[18]

The most commonly used lateral window technique has potential complications such as membrane perforation, bleeding, infection and sinus obstruction.[98] This technique requires considerable surgical skill and time, giving rise to unpleasant sequelae such as edema and discomfort.

A less invasive technique (Bone Added Osteotome Sinus Floor Elevation) proposed by Summers resulted in a modest bone height increment of 3±0.8mm.[53] Complications associated with this technique include membrane perforation, tears and BPPV.[56] So current trend centers on the development of minimally invasive techniques, which are designed to minimize the post-operative morbidity while achieving maximal augmentation of the sinus.

The present study was undertaken to assess the safety and efficacy of a minimally invasive technique (MIAMBE) for maxillary sinus elevation using the Sinus lift Balloon system (Zimmer Dental); followed by augmentation of the sinus with Irradiated Cancellous Bone Allograft (Rocky Mountain). The implant placement was planned after a six month follow-up period.

It is generally preferred to delay implant placement by several months after the grafting phase, to allow adequate graft maturation. The matured bone graft is predominantly responsible for both mechanical and biological implant stability, thereby providing more implant –bone contact and a more favorable prognosis for implant survival.[41] On the basis of these considerations, delayed implant placement was planned, after 6 months of sinus augmentation.

In the present study, the radiographic assessment was based on panoramic radiographs. Although CT scan is considered to be the most accurate means for the diagnosis of sinus pathologies and for the evaluation of sinus membrane thickness, however periapical and panoramic radiographs were also frequently used to diagnose radiodensities and mucosal cysts.[10] OPG can only be used for the assessment of bone height because it offers only a two-dimensional view, therefore volume measurement could not be assessed.[57]

A minimum of three panoramic radiographs were taken; at baseline, 3 months and 6 months postoperatively. A single manual tracing of the alveolar crest, original sinus floor and the grafted sinus floor was performed on tracing paper overlying the radiographs.

Studies have reported the mean magnification of 24.5% on panoramic radiographs.[57] Compensation for this error was mandatory; OPG was taken using a metal ball stent and the comparison was made with the manufactured dimensions, for correction of magnification error on panoramic radiographs. This provided a reliable method to compensate for the magnification presented.

The point A presented with a mean increase in bone height of 2.3mm during the 3 month follow-up period, which consistently increased to 2.7mm during the 6 month follow-up period.

There was a significant increase in MBH by 3.2mm at the point B from the baseline, which had a relatable increase of 3.34mm during the 6 month follow-up period.

The point C presented with a consistent increase of about 1.8mm and 2mm in MBH during the 3 month and 6 month follow-up period respectively, so as to allow implant placement in future.

This study utilized irradiated allogenic cancellous bone and marrow (RMTB) for augmentation of the sinus. Though autogenous bone graft has been considered the gold standard; the use of bone substitutes can result in reduced treatment morbidity by eliminating the need for harvesting autogenous bone from secondary surgical sites.[41] Mineralized cancellous bone allograft (MCBA) has been used as a grafting material in the treatment of periodontal bone defects, in ridge augmentation or sinus augmentation before, or concurrent with, implant placement.[5]

Allogenic bone-graft materials generally provide a scaffold across a defect or in a cavity into which host bone cells migrate to, eventually generate bone via osteoinduction (demineralized graft) or osteoconduction (mineralized graft). It is desired that an ideal maxillary sinus grafting material must trigger the formation of viable bone at a high rate after the graft material matures. It is also desired that the material be capable of preventing repneumatization during the resorption of grafting material.[96] Mineralized cancellous bone allograft demonstrated a vital bone content of 25.2% in the grafted sinus, after a healing period of 9 months.[73]

The reduction in graft height in the sinus was found more with allografts when compared to alloplasts, the reason being that the alloplasts serve as a scaffold and conducts osseous growth around and through its particles, whereas allografts proposed to both induct and conduct osseous healing.[51] Thus from a biologic stand point, the larger the sinus, the longer

the maturation time that is required for a sinus grafted with cancellous bone allograft to achieve a similar level of vital bone as a sinus grafted with autogenous graft.[52]

MIAMBE was performed in patients with the residual alveolar bone height of 5mm or more; because of the desire for placement of longer implants. **Toffler** et al (**2004)**[83] suggested the minimal implant length of 8.5mm or more was adequate in the maxillary posterior region.

Osteotomes are also used as a part of minimally invasive technique to obtain a small localized elevation of the sinus floor.[11]

As an alternative to standard drilling, end cutting osteotomes are used to gradually expand the osteotomy, compressing and apically displacing the cancellous bone within the confines of the cortical plates and thus improving localized bone density. The improved density of the implant site enhances the implant's primary stability.[75]

Aforementioned studies support the use of osteotomes; hence this study utilized osteotomes (bone expanders) as a part of the minimally invasive procedure.

No complications were observed, during or after the surgical procedure. None of the patients exhibited sinus pathology during the 6 month follow-up period. This was probably the result of meticulous

surgical protocol, patient selection and the minimal invasiveness of the sinus-lift balloon system.

MIAMBE resulted in satisfactory bone augmentation and also eliminates the complications and discomfort associated with traditional lateral window technique. Because it is minimally invasive, this technique may be used as an alternative to the currently employed maxillary sinus augmentation methods.

# SUMMARY AND CONCLUSION

The study titled "Clinical and radiographic evaluation of sinus floor augmentation utilizing Irradiated Cancellous Bone Allograft (RMTB), using Sinus-lift balloon system (Zimmer Dental)" enrolled nine patients seeking posterior maxillary region implant placement.

After administration of local anesthesia and alveolar crest exposure, the osteotomy site was prepared using osteotomes, followed by sequential balloon inflations yielding > 10 mm of sinus membrane elevation. Augmentation of the sinus was done utilizing the Irradiated Cancellous Bone Allograft (RMTB). The study was evaluated for a 6 month period, with the vertical bone height being assessed at, the baseline, 3 months and 6 months post- operatively with the aid of OPG.

Within the limits of this study, the following conclusions have been elucidated:

1. This minimally invasive antral membrane balloon elevation (MIAMBE) procedure using Sinus-lift balloon system (Zimmer Dental) is safe and effective for maxillary sinus augmentation. The procedure yielded satisfactory bone augmentation results.

2. This procedure eliminates the complications, discomfort and also shortens the surgical time associated with the traditional lateral maxillary sinus approach.
3. Particulate irradiated cancellous bone allograft (RMTB) augmentation resulted in being bio-compatible and seemed to improve new bone formation in sinus grafting. It can be used as a substitute for autogenous grafts in sinus augmentation procedures.

The success of this procedure depends on proper pre-operative assessment, treatment planning, careful execution of the surgical technique and post operative follow up.

Thus, it is appropriate to conclude that, sinus floor elevation using "Sinus-lift Balloon System (Zimmer Dental)" has obvious advantages, paving way for maximal augmentation of the sinus for successful implant placement in future. Because it is minimally invasive, this technique may be used as an alternative to the currently employed maxillary sinus augmentation methods.

However, further controlled clinical trials with large sample size, advanced radiographic and histomorphometric analysis should be executed to evaluate the effectiveness and safety of this technique compared to other sinus augmentation procedures.

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# ARMAMENTARIUM

**Fig.1a: Surgical Instruments**


**Fig.1b: Physio - Dispenser with Internal Irrigation System**


**Fig.1c: Bone Expanders**


**Fig.1d: Bone Condensers**

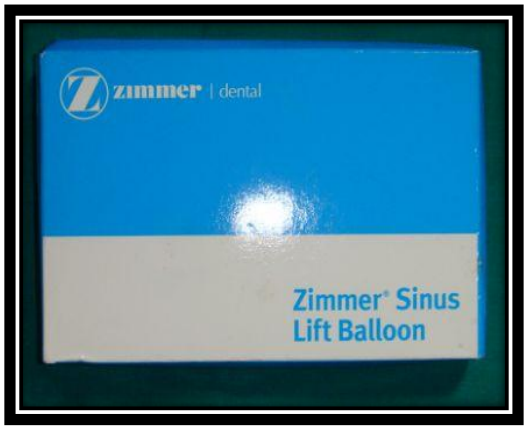


**Fig.1e: Sinus-Lift Balloon System**

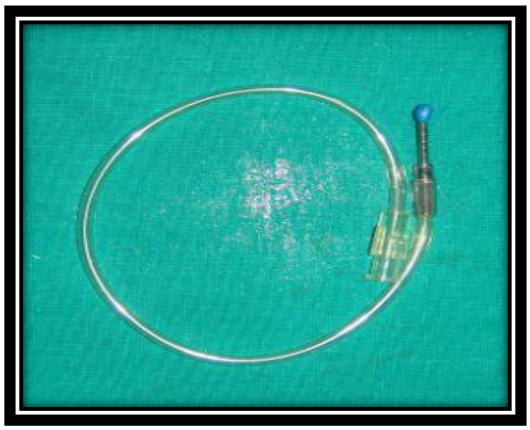

**Fig. 1g: Deflated Balloon**

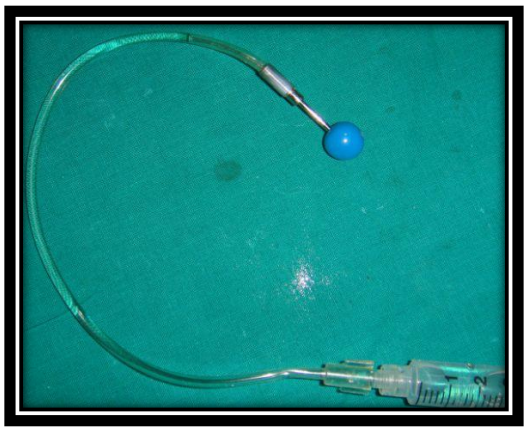

**Fig.1h: Balloon Inflated with Saline**

**Fig.1f: Bone Graft (RMTB)**

**SINUS AUGMENTATION SURGICAL PROCEDURE**

**USING "SINUS LIFT BALLOON SYSTEM"**

**Case No.1 – Clinical View of the Procedure**

**Fig.2a: Pre-Operative View**

**Fig.2b: Crestal Incision Placed**

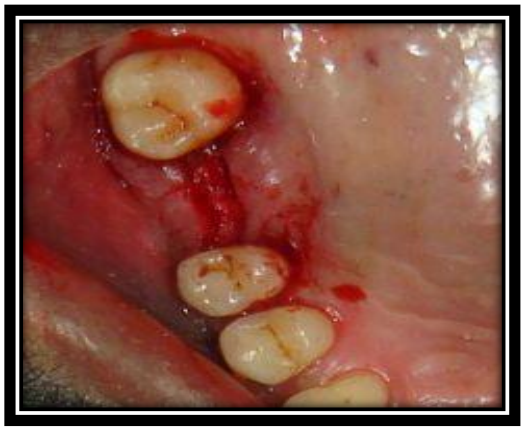

**Fig.2c: Muco Periosteal Flap Elevated**

**Fig.2d: Osteotomy Prepared Using Osteotomes**

**Fig.2e: Balloon secured into Osteotomy site**

**Fig.2f: Inflation of Balloon using Saline**

**Fig.2g: Bone Graft packed in the Osteotomy Site**

**Fig.2h: Simple Interrupted Sutures Placed**

**Case No 1- Radiographic View of the Procedure**

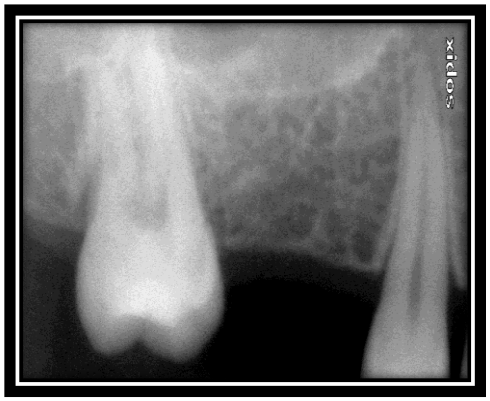

**Fig.2i:Pre-Operative View**

**Fig.2j: Depth gauge placed in Osteotomy Site**

**Fig.2k: Osteotomy prepared using Osteotomes**

**Fig.2l: Osteotomy prepared using Osteotomes**

**Fig.2m: Inflated Balloon in the Osteotomy Site**

**Fig.2n: Bone Graft condensed in the Osteotomy site**

**Case No 1 - VBH Measurement using OPG**

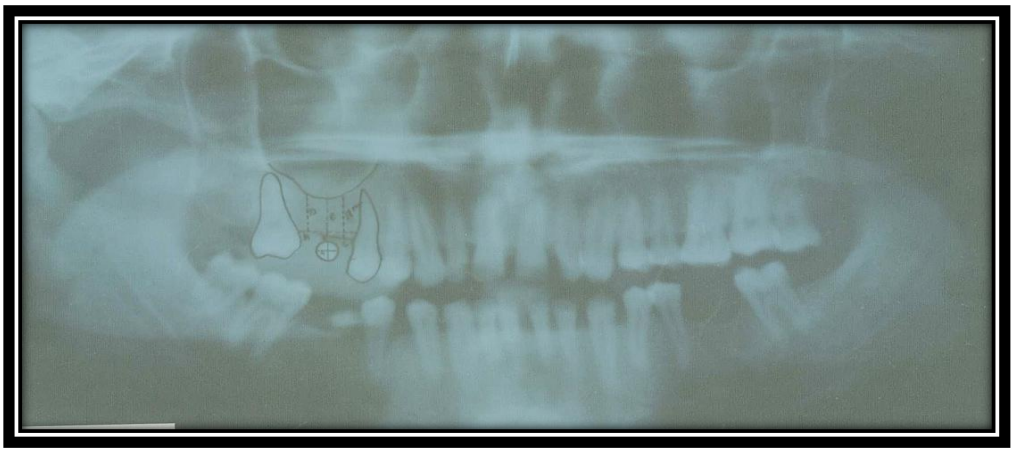

**Fig.2o: Pre-operative OPG**

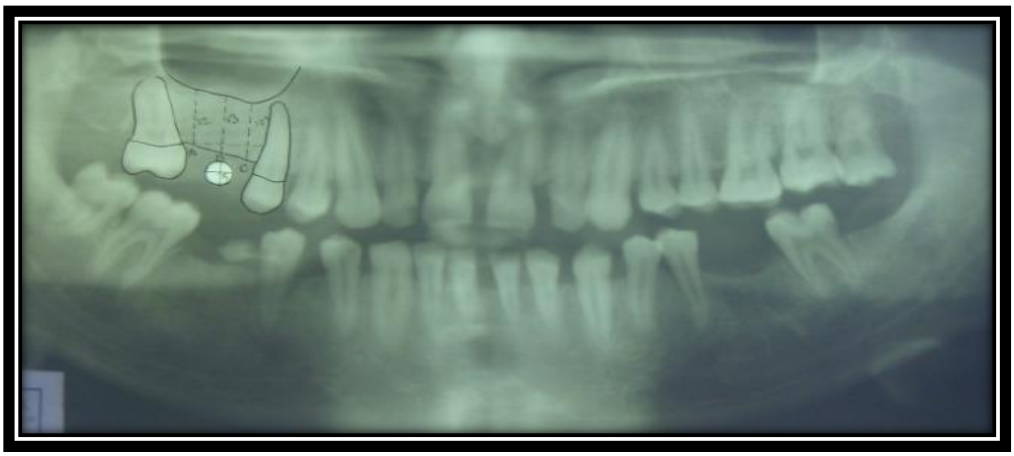

**Fig.2p: Post-operative OPG (3 months)**

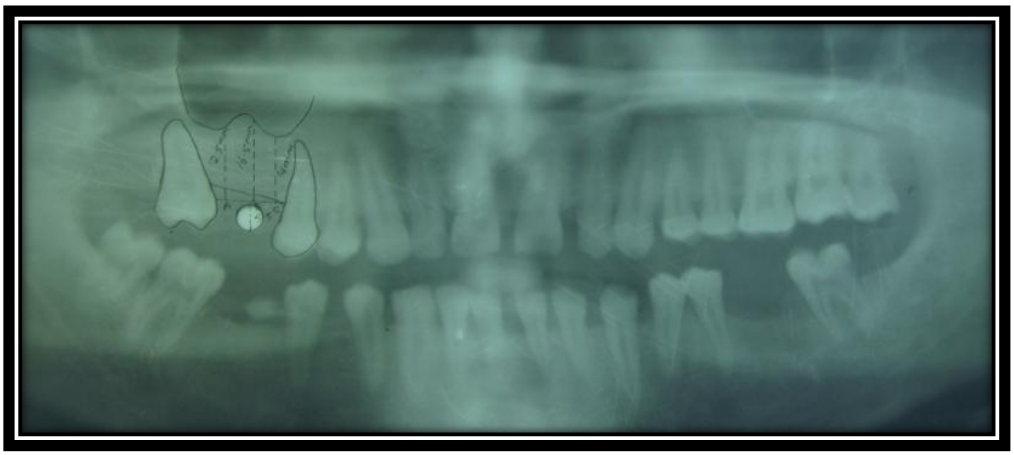

**Fig. 2q: Post-operative OPG (6 months)**

**Case No 1- Implant Placement**

**Fig. 2r: Implant placed in grafted sinus (clinical view)**

**Fig. 2s: Simple Interrupted sutures placed**

**Fig. 2t: Grafted Sinus (6 months Post-operative view)**

**Fig. 2u: Depth gauge in Osteotomy Site**

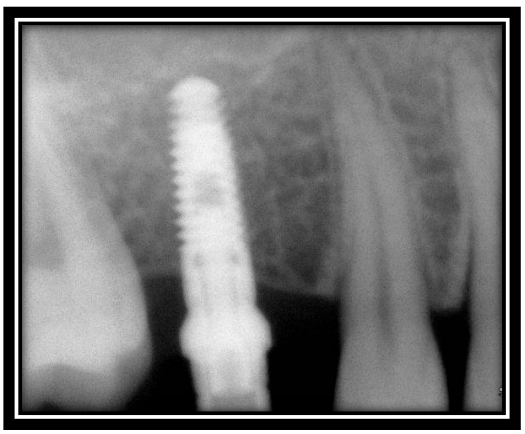

**Fig. 2v: Implant placed in grafted sinus**

**Case No 2- Clinical View of the Procedure**

**Fig.3a: Pre-operative View**

**Fig.3b: Osteotomy prepared using Pilot Drill**

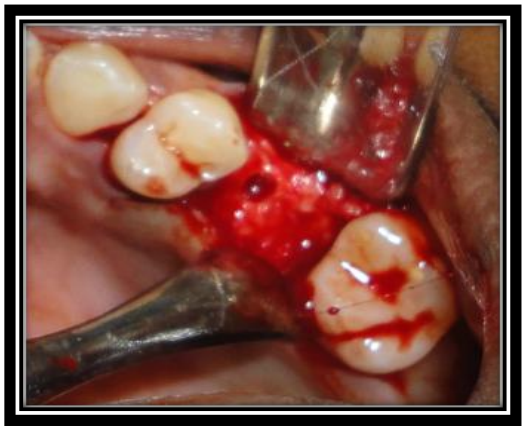

**Fig. 3c: Osteotomy Site**

**Fig. 3d: Bone Graft condensed in the Osteotomy site**

**Fig. 3e: Simple Interrupted Sutures Placed**

**Case No 2 - Radiographic View of the Procedure**

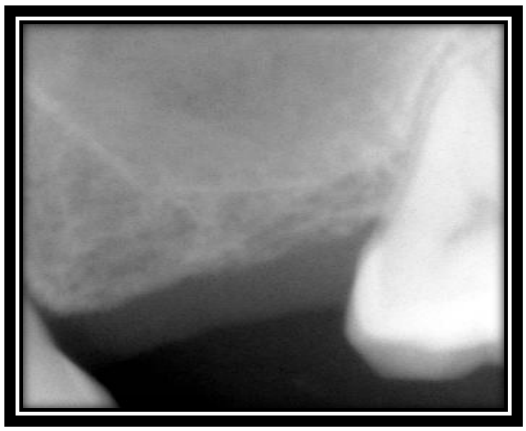

**Fig. 3f: Pre-operative View**

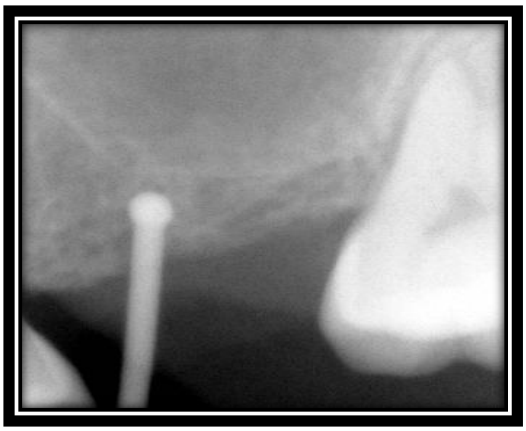

**Fig. 3g: Depth gauge in Osteotomy Site**

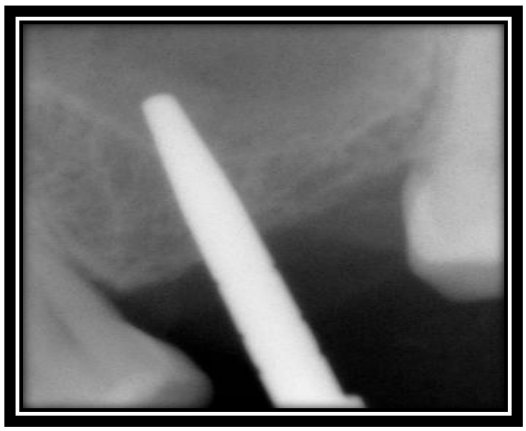

**Fig. 3h: Osteotomy prepared using Osteotomes**

**Fig. 3i: Osteotomy prepared using Osteotomes**

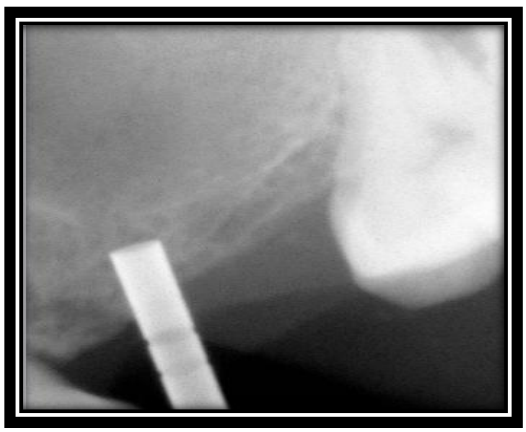

**Fig. 3j: Inflated Balloon in the Osteotomy Site**

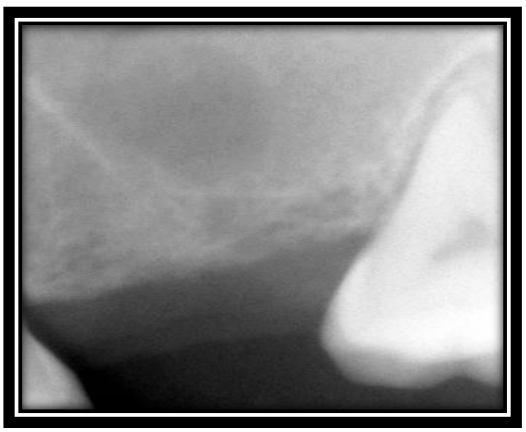

**Fig. 3k: Bone Graft condensed in the Osteotomy Site**

**Case No 2 - VBH Measurement Using OPG**

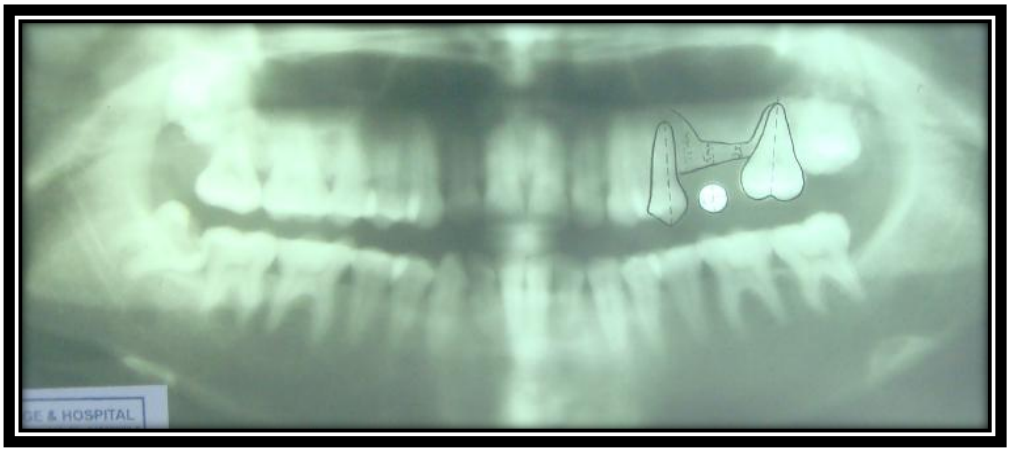

**Fig. 3l: Pre-operative OPG**

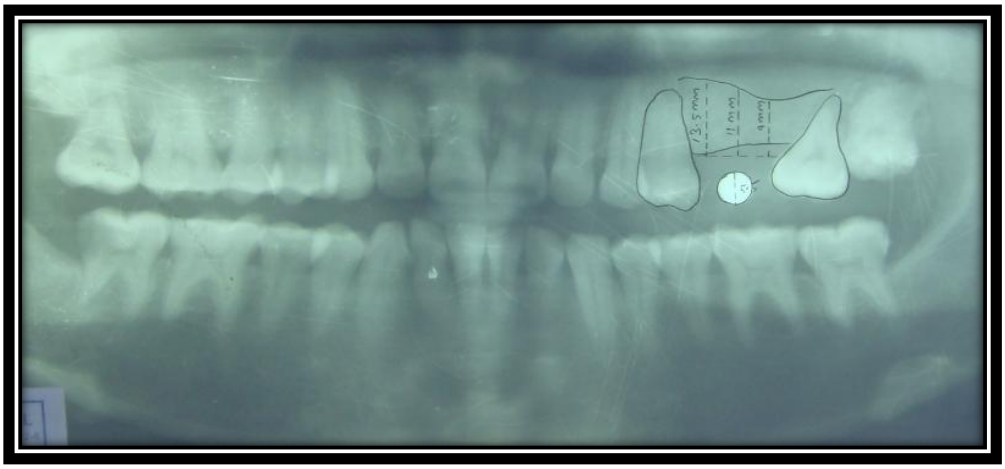

**Fig. 3m: Post-operative OPG (3 months)**

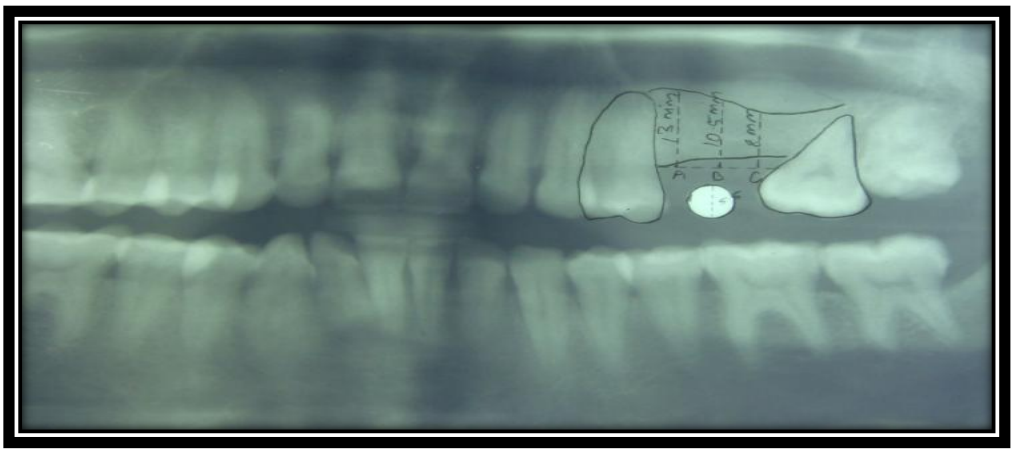

**Fig. 3n: Post-operative OPG (6 months)**

**Case No 3 - Clinical View of the Procedure**

**Fig. 4a: Pre-operative view**

**Fig. 4b: Crestal Incision placed**

**Fig. 4c: Muco Periosteal Flap Elevated**

**Fig. 4d: Osteotomy prepared using Pilot Drill**

**Fig. 4e: Osteotomy prepared using Osteotomes**

**Fig. 4f: Inflation of Balloon using Saline**

**Fig. 4g: Bone Graft placed in Osteotomy site**

**Fig. 4h: Bone Graft condensed in the Osteotomy site**

**Fig. 4i: Simple Interrupted Sutures placed**

**Case No 3-Radiographic View of the Procedure**

**Fig. 4j: Pre-operative View**

**Fig. 4k: Osteotomy prepared using Osteotomes**

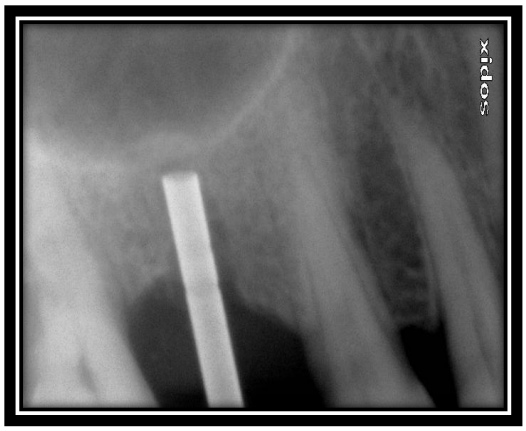

**Fig. 4l: Inflated Balloon in the Osteotomy Site**

**Fig. 4m: Bone Graft condensed in the Osteotomy site**

**Case No 3-VBH Measurement Using OPG**

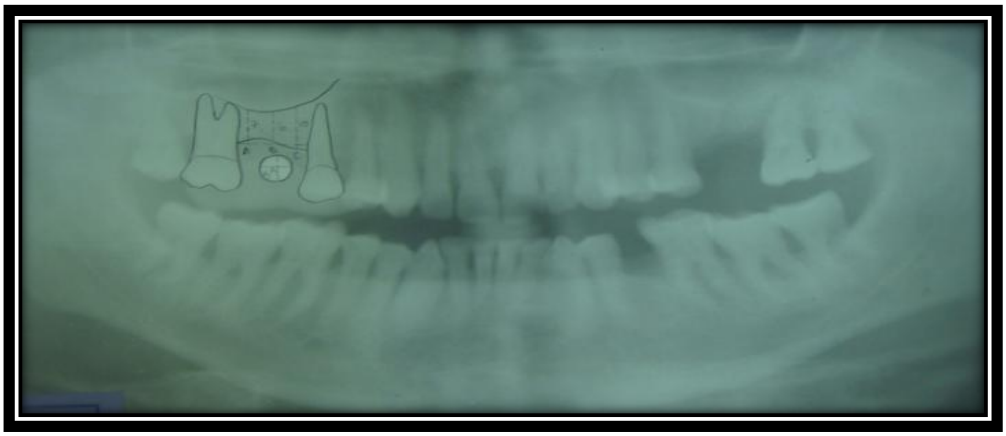

**Fig. 4n: Pre-operative OPG**

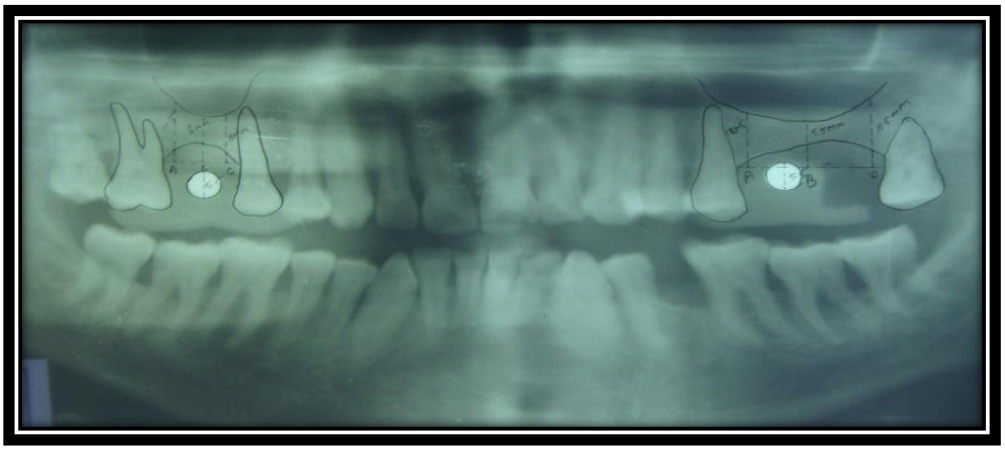

**Fig. 4o: Post – operative OPG (3 months)**

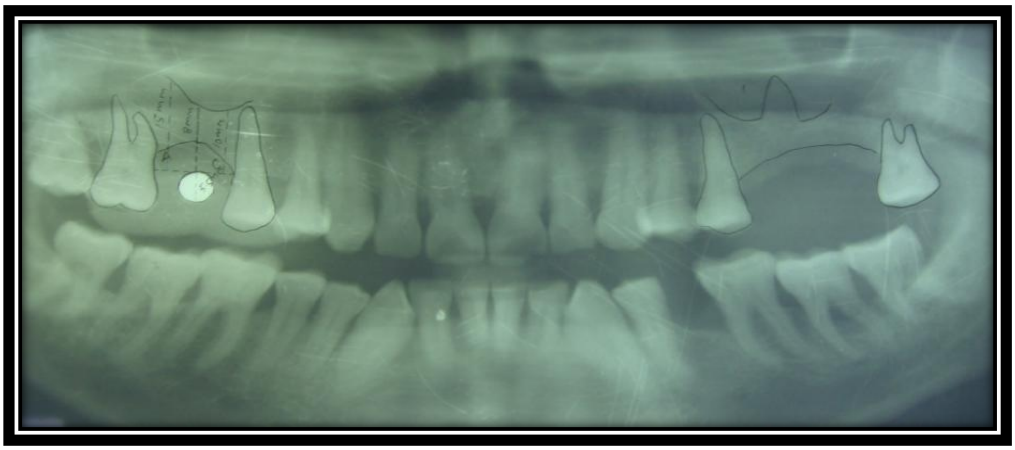

**Fig. 4p: Post – operative OPG (6 months)**